UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,242	05/25/2001	Anthony L. Fitzhugh	17363-38	3958

7590 06/04/2002

OPPENHEIMER WOLFF & DONNELLY LLP
38th Floor
2029 Century Park East
Los Angeles, CA 90067

EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/865,242	FITZHUGH ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *29-31* is/are allowed.

6)☒ Claim(s) *15-17,20,23 and 25-28* is/are rejected.

7)☒ Claim(s) *18,19,21,22,24 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of paper number 5 filed 03/15/02. Claims **15-32** are pending and not claims 6-36 as stated in line 4 form the bottom of page 3 of the response filed 03/15/02.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating or inhibiting restenosis, does not reasonably provide enablement for "preventing" restenosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The asserted utility is not believable on its face. It is not known how a method wherein a composition is claimed can be administered to prevent restenosis. It is not known how the occurrence of a pending restenosis can be precisely predicted in a subject as to when and how the condition will occur and to administer the claimed composition to prevent the occurrence.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

1) Breadth of claims.

2) Nature of invention.

3) State of prior art.

4) Level of ordinary skill in the art.

5) Level of predictability in the art.

6) Amount of direction and guidance provided by the inventor.

7) Existence of working examples

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The present invention is directed to treating or inhibiting restenosis by administering a stent or graft or guard wire or catheter whose surfaces are coated lubricious coating and where nitric oxide releasing nucleophilic compound is dispersed through out the coating. The state of the art is what prior art knows about the invention. There is no known art wherein a certain composition is administered to successfully prevent restenosis before the occurrence.

The level of ordinary skill is high but only in the art of treating or inhibiting restenosis. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants. However, the amount of direction and guidance provided by the applicants is limited to treatment or inhibition. There is no evidence in the specification that established correlation between the experiment and the claimed utility. See Ex parte Mass, 9 USPQ2d 1746, 1987. The quantity of experimentation required to use the

method as claimed in the instant invention, based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of in-vivo experiments as well as assays.

4. Claims 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Lines 3-5 of claim 25 are confusing.

Claim Objections

5. Claim 19 and 32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 19 and claims 21 and 22 that depend from claim 19 and claim 32 have not been further treated on the merits.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 15, 16, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Stamler et al. (us 5,770,645)

Stamler teaches a medical device that is coated with hydrogel for delivery of nitric oxide to a treatment site in an individual or animal (abstract, column 2, lines 48-67, column 3, lines 59-

65). The medical device can be a stent and the device is implanted to reduce platelet deposition and restenosis (column 2, lines 2-10 and column 10, lines 5-67). The teachings of Stamler meet the limitations of the claims.

8. Claims 15-17, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Ragheb et al. (US 5,873,904).

Ragheb teaches an implantable medical device (abstract and column 4, lines 33-51) that is configured as a stent, catheter, wire guide, a cannula, vascular or other graft and cardiac pace maker lead or lead tip (column 8, lines 20-37). Nitric oxide or nitric oxide promoter are examples of bioactive material that can be delivered by the medical device to treatment sites (column 10, lines 66 and 67 and claim 12). The medical device is coated with polymeric materials selected from acrylate, methacrylate, cyanoacrylate and acrylic polymers and copolymers (column 13, lines 2-26, and 40-60). Ragheb anticipates the claims.

9. Claims 18 and 24 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 29-31 are allowable because the prior art does not teach a method of coating a medical device with polyethylenimine according to the steps of claim 29.

11. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
May 31, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600